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PHARMACEUTICAL BIOTECHNOLOGY EDUCATION IN THE PHARMACY CURRICULUM AT EUROPEAN UNIVERSITIES

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ABSTRACT

The aim of our study was, firstly, to review the scientific literature available on the pharmaceutical biotechnology education in the European Union, and, secondly, to systematize the approaches that the universities apply to address the issue. A literature search was performed and the information about the curricula in the biotechnology-related disciplines included in the pharmacist education in the European universities was obtained from the universities' websites. In total, 130 universities' web sites were searched and the available information about 81 universities was used. Our study showed that there is no unified approach to biotechnology in the studied universities. There are three approaches chosen by the universities to address biotechnology in the pharmacy curriculum: distribution of biotechnology topics throughout the curriculum, offering a compulsory pharmaceutical biotechnology course, or elective/optional course in addition to biotechnology topics in other disciplines. However, the majority (60%) have chosen to incorporate various biotechnology subjects throughout the pharmacy curriculum and just 9% add an elective course in pharmaceutical biotechnology.

The significant number of biotechnology-derived medicinal products available to the European patients has influenced the pharmacy education. A unified and better organized approach to pharmaceutical biotechnology in the EU with special attention to production and distribution of biotechnology medicinal products will benefit the education.

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Introduction

Pharmaceutical biotechnology is one of the major advances that give a new direction to pharmaceutical sciences. To meet the needs of this new dynamic era of pharmaceutical research and health care environment, pharmaceutical education has to set new priorities in order to keep pace with the challenges related to genomic technologies (21). The development of new educational courses in pharmacy curricula is focused on preparing pharmacists oriented not only for pharmacy practice, but also for drug research and development, pharmaceutical industry, academic research, etc. (6). There are studies on the inclusion of biotechnology in the pharmacy schools in the USA (8, 12, 13, 16, 17, 19) but there is no systematized information about European universities with the exception of the reports available from the PHARMINE project (2) and very few studies made for selected countries (11, 22).

The aim of our study was, firstly, to review the scientific literature available on the pharmaceutical biotechnology education in the European Union, and, secondly, to systematize the approaches that the universities apply to address the issue.

Materials and Methods

Literature search was done through MEDLINE/PubMed, Scopus database search as well as an Internet-based search with key words "pharmacy", "biotechnology", "biotechnology pharmaceutical education", "biopharmaceuticals" and "European Union". For the period 2001–2011 we found a total of 5 publications satisfying the search criteria. We have limited the search only to publications related to the universities in the European Union, as the USA pharmacy schools were studied in our previous publication (19). The articles were systematized in historical order according to the date of publishing.

The information about the curricula of the biotechnology-related disciplines included in the pharmacists' education in the European universities was taken from the universities' websites. In total, 130 universities' web sites were searched and the available information for 81 universities was classified according to the availability of pharmaceutical biotechnology as: 1) a subject in the regular pharmacy undergraduate education; 2) as integrated biotechnology-related content in different subjects in the undergraduate program; 3) as an elective course in undergraduate pharmacy education; and 4) as double master (pharmacy biotechnology) degrees.

The present publication is limited to the universities in the EU with publically available curriculum information only.

Results and Discussion

General principles and recommendations for biotechnology education in the pharmacy curriculum in EU universities

Within mainland Europe, pharmacy degree programs are typically 5 to 6 years. The shortest of the European pharmacy degrees is the United Kingdom's 4-year degree program (15). Entry qualifications vary slightly across the universities

offering MPharm programs in EU, but the most important deciding factor for most applicants is performance in the national school-leaving examinations. Some universities put great emphasis on performance at interview and use this as an important factor in their selection process, others prefer recommendations. Nevertheless all universities put forward a high EU standard for pharmacy education in order to ensure that the pharmacy education supply meets the demands of the practice.

The PHARMINE project, which was funded with support from the European Commission and aimed at gaining hard data on pharmacy and pharmacy education in Europe, assessed about 290 individual institutions, created a database of universities and surveyed the teaching and learning methods applied in pharmacy study; impact of the Bologna principles (3); pharmacy curriculum; impact of EC Directive 2005/36/EC (9) on the course length and content and traineeship and the applied quality assurance systems (2). One hundred and ninety-five faculties of pharmacy in 25 EU member states (the project excludes Cyprus and Luxembourg) were included in the project with an average number of students of 817 ± 385. Biotechnology is recommended as a mandatory subject in PHARMINE competency curriculum for industrial pharmacy in Europe both in the master level and post-graduation level (14), as the knowledge of the production, quality assurance and applications of biotechnology, nanotechnology and genomic medicines are necessary for the biotechnology-shaped modern pharmacy practice.

Scientific publications about the biotechnology education as part of pharmacy education in Europe

The inclusion of biotechnology in pharmacy education is a widely discussed subject due to the changing environment, advances in pharmaceutical technology and the increasing demand for pharmacists' educated in biotechnology (4). As Brodie et al. (5) wrote in 1985, a new philosophical basis for pharmacy education that is consistent with the needs of a technologically oriented society is needed. According to Stewart et al. (18) the curriculum of students undergoing training in pharmacy should cover such areas as immunoglobulin, immunomodulators, growth hormones, targeted drug-delivery systems, and advanced diagnostic techniques that use biotechnology products.

Withott (23) shared the opinion that the achievements of biotechnology in pharmaceutical science and practice created new opportunities for universities to reform their educational programs in biology, medicine and pharmacy accordingly. A survey of 52 pharmaceutical faculties/pharmaceutical biotechnology companies in Europe, Asia and America regarding their views about creation of a satisfactory program of pharmaceutical biotechnology was done in 2001 (7). All participants in the survey were in agreement about the inclusion of pharmaceutical biotechnology courses in the undergraduate teaching programs of the Faculties of Pharmacy. Most of the responding faculties in Europe stated that there were pharmaceutical biotechnology courses in their pharmacy curriculum. Evaluation of the responses from Europe showed that suggestions for the duration of courses was variable from 1 to 7 hrs/week, while the initiation time of courses was proposed to be the 3rd and 4th years. However, almost 50 % of the respondents suggested that these should be optional.

The participants in the Pharmacogenomics Education Forum held on 2 October 2004 during the 3rd Annual Meeting of the International Society of Pharmacogenomics (ISP) and the Education Subcommittee of the ISP issued a 'Background Statement' and 'Recommendations and Call for Action' addressed to Medical, Pharmaceutical, and Health School Deans of Education, which called upon incorporation of pharmacogenomics in the core teaching curricula of pharmacology (10). The authors considered it vital for ensuring successful implementation of personalized medicine into medical practice later, in pace with the emergence of the latest genomic diagnostics tools.

Walsh et al. (22) performed a 13-question survey in 2007. It was commissioned by the European Association of Pharma Biotechnology (EAPB) and focused upon the lecture complement of biochemistry, microbiology, molecular biology and pharmaceutical biotechnology taught within European pharmacy undergraduate degree programs. The survey covered 15 European countries. The mean numbers of lecture hours delivered in biochemistry, microbiology and molecular biology were 61.8 ± 32.2, 52.4 ± 27.7 and 34 ± 16.4, respectively. The authors found that for each subject, the number of lectures differed significantly between the different institutions. Thirty-three (85 %) of the 40 survey responders included core or elective courses in pharmaceutical biotechnology (mean number of lectures delivered 29.9 ± 18.6, mainly in the third or fourth year). Very significant variation in the pharmaceutical biotechnology course content was also observed.

Systematization of the information on biotechnology in pharmacy curriculum at EU universities

We reviewed the pharmacy curriculum in 81 universities in the EU. The distribution of the studied universities amongst the countries is given in **Fig. 1**. The distribution of universities according to the approach preferred regarding the inclusion of the pharmaceutical biotechnology content in the pharmacy curriculum is shown in **Fig. 2**. Sixty percent of the universities searched (n = 49) have incorporated biotechnology topics throughout the pharmacy curriculum. For example, the pharmacy curriculum at the Goethe University Frankfurt/Main, Germany, has the following biotechnology knowledge incorporated throughout the 8 semesters: systematic classification and physiology of drug-producing organisms part I and part II (part of pharmaceutical biology lectures during the 1st and 2nd semester respectively), genetics (2nd semester), lectures in immunology, vaccines and sera (5th semester), recombinant drugs (6th, 7th and 8th semester), methods of pharmaceutical biotechnology (6th and 7th semester), drugs of herbal or microbial origin (6th, 7th and 8th semester) and

biopharmaceuticals (8th semester). A biotechnology incubator, the Frankfurt Centre for Innovation (FIZ), supports the knowledge transfer between fundamental research and new business. Part of the research in the department is organized in interdisciplinary research centres.

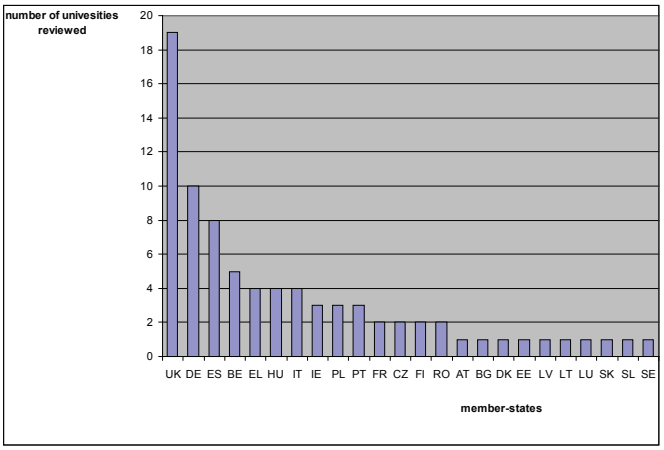

Fig. 1. Distribution of studied universities per country

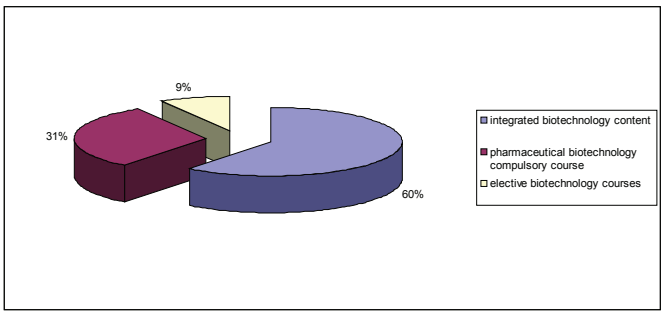

Fig. 2. Content of biotechnology in pharmacy study in EU universities

In 15 out of 19 UK universities included in our study biotechnology content is distributed throughout the pharmacy curriculum in disciplines such as cellular biology, biochemistry, pharmacogenomics, pharmaceutical technology, pharmacology, pharmaceutical legislation, pharmaceutical chemistry etc.

The same approach was chosen by universities in Italy, all Hungarian and Finnish universities, 50% of the universities in Greece, two Belgian universities as well as the Royal Danish School of Pharmacy in Copenhagen, the University of Luxembourg, Kaunas Medical University in Lithuania and Rīga Stradiņš University in Latvia.

Thirty-one percent of the studied universities (n = 25) offer specialized compulsory courses in pharmaceutical biotechnology, e.g. Liverpool John Moores University, Queen's University of Belfast and University of Brighton in the UK, University of Ljubljana in Slovenia, Medical University of Gdansk in Poland, University of Patras and Aristotle University of Thessaloniki in Greece, University of Tartu in Estonia etc. All three universities in Ireland and Portugal which offer pharmacy education have included in their curriculum compulsory biotechnology courses. The same approach is used also by three universities in Belgium (Vrije University Brussel, Universiteit Gent and University of Antwerp) and seven universities in Germany. In Vrije University in Brussels the compulsory course in pharmaceutical biotechnology is taught during the third year of the Bachelor's degree and repeats the basic elements of molecular biology with an emphasis on working with recombinant DNA and expression systems in procaryotic cells, eukaryotic cells and transgenic animals. The course also includes topics such as production of biotechnological pharmaceuticals (culture, downstream processing, formulation etc.), therapeutic classes of biotechnological drugs, bio safety and marketing authorization of biotechnology products.

At the University College of Cork, the compulsory course in pharmaceutical biotechnology is taught during the 4th year. The study content is focused on the genetic basis of diseases; whole cells and enzymes in the production of chiral, enantioenriched APIs, pharmaceutical intermediates and fine chemicals; stability and purity of biotech products; analytical techniques for biotech products; molecular techniques; production and downstream processing of biotech products. Special attention is given to the production and isolation of recombinant protein drugs (insulin, haematopoietic growth factors, interleukins and interferon, growth hormones, monoclonal antibody-based pharmaceuticals, recombinant tissue-type plasminogen activator etc); protein–protein interactions; formulation and delivery of biotech products; pharmacokinetics and pharmacodynamics of peptide and protein drugs; gene therapy and vaccines.

In Germany, the majority of universities offer compulsory biotechnology courses as part of pharmaceutical biology study and the content is taught either during the 5th–7th semester or 6th and 8th semester. Special attention is paid to the drugs of microbial origin. The biotechnology course in Liverpool John Moores University offers up-to-date knowledge on neoplastic diseases, AIDS, malaria, fungal and selected bacterial diseases and their pharmacological treatment (prophylactic and therapeutic). Pharmaceutical biotechnology is taught during the 4th year in Poznan University of Medical Sciences and Medical University of Gdansk in Poland; Trinity College Dublin and Royal College of Surgeons in Ireland, University of Patras and Aristotle University of Thessaloniki in Greece etc.

Only 9% of the studied universities (**Fig. 2**) introduced elective/optional courses in pharmaceutical biotechnology with special emphasis on biotechnology-derived medicinal products and gene therapy in addition to the biotechnology topics incorporated throughout the pharmacy curriculum in various subjects. Some universities offer doubled master's program (pharmacy and biotechnology) like the School of Health Sciences in Madrid (20). In addition to the traditional pharmacy education subjects, students who have chosen the double degree study molecular genetic engineering, pharmaceutical biotechnology, food technology and legislation, protein chemistry and engineering, cell cultures, bioreactors, biotechnological products and processes etc. which gives an excellent background for pharmacists needed

TABLE 1

Content of biotechnology in Faculty of Pharmacy, Medical University – Sofia

Subject	Lectures/ contact hours	Seminars/ contact hours	Relative share of biotech topics	Total	ECT
Molecular biology	30	30	50 %	60	4
Genetics	15	15	50 %	30	2
Pharmacology	60	120	15 %	180	12
Pharmaceutical technology, part I	60	150	15 %	210	14
Pharmaceutical technology, part II	60	165	15 %	225	15
Pharmaceutical chemistry	90	135	15 %	225	15
Biopharmacy and pharmacokinetics	30	90	50 %	120	8
Pharmaceutical biotechnology	30	60	100 %	90	6

for the biotechnology-shaped pharmaceutical industry. The double degree in pharmacy and biotechnology program takes 6 years.

Biotechnology in the pharmacy curriculum in Bulgaria

According to the Bulgarian Drug Agency annual report, six of the top 10 most used medicinal products (by value) in 2009 were biotech medicinal products, namely epoetin beta, trastuzumab, one particular pre-mixed insulin, imatinib and rituximab which were market authorized through the centralized procedure and olanzapine, authorized through the national procedure. They account for 6.3 % of the market value (1). This tendency is reflected by the pharmacy curriculum in the Faculty of Pharmacy, Medical University – Sofia, where, in addition to the biotechnology subjects incorporated throughout the pharmacy curriculum, there is an elective course in pharmaceutical biotechnology in the 7th semester. The content of the program associated with biotechnology is given in **Table 1**. The credit for the elective biotechnology course is 6, while the similar courses in the studied EU universities have 3 ± 1 ECT. The program contains topics related to biotechnology-derived medicinal products, biotechnology production processes, especially in herbal medicines cultivation, extraction and growth of plants. It also presents main terminology and safety aspects of biotechnology products.

Our study showed there is no unified approach to biotechnology in the studied EU universities. There are three approaches chosen by the universities to address biotechnology in the pharmacy curriculum: distribution of biotechnology topics throughout the curriculum; offering a compulsory pharmaceutical biotechnology course, or elective/optional course in addition to biotechnology topics in other disciplines. However, the majority (60 %) have chosen to incorporate various biotechnology subjects throughout the pharmacy curriculum and just 9 % have added an elective course in pharmaceutical biotechnology. We did not find any information available for pharmaceutical biotechnology as postgraduate specialization. A significant number of universities (31 %), in addition to biotechnology subjects incorporated throughout the curriculum, offer pharmaceutical biotechnology compulsory course.

In light of the results of a similar study regarding the content of biotechnology in the pharmacy curriculum in the USA pharmacy schools, this percentage is very high (compared to 19 %) (19). Biotechnology helps the pharmacy students to understand the genetic basis of diseases, to evaluate the factors influencing the production of biotechnology pharmaceutical products, to understand the regulatory issues associated with biotechnology products, gene targeting treatment strategies and impact of various factors that influence the stability of biopharmaceutical formulations. In comparison with the USA, much more universities in the EU have decided on development of compulsory specialized courses in pharmaceutical biotechnology. However, we recognize that the study was limited to the universities with publicly available curriculum information.

Regardless of the approach chosen, undergraduate pharmacists are provided with knowledge, skills, required for biotechnology-driven pharmaceutical industry and pharmacy practice.

Conclusions

The significant number of biotechnology-derived medicinal products available to the European patients have influenced the pharmacy education. A unified and more structured approach to pharmaceutical biotechnology in the EU with special attention to production and distribution of biotechnology medicinal products will benefit the education. The adequate reflection of biotechnology-related developments in modern pharmaceutical science and practice in the pharmacy curriculum is an important tool for ensuring safe and rational use of biopharmaceutical products.

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